

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

Track Three Cases

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

**DECLARATION OF STEVEN N. HERMAN IN SUPPORT OF THE PHARMACY
DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS
AND TESTIMONY OF DR. KATHERINE KEYES**

EXHIBIT 6

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK: PART 48

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IN RE: OPIOID LITIGATION

INDEX NO.: 400000/2017

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September 10, 2020
Central Islip, New York

MINUTES OF FRYE HEARING
(Testimony of Dr. Keyes)

B E F O R E: HON. JERRY GARGUILO
 Supreme Court Justice

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information on the dollars that were -- the payments to doctors for opioid products.

Q. Do you know who maintains Open Payments?

A I'm not sure off the top of my head.

Q. Is it a federal agency?

A I believe so. I believe it was the result of a -- there was a law that was passed saying that these data had to be made public.

Q. Did Hadland in this study interview doctors?

A No.

Q. Did Hadland review marketing materials?

A Not as far as I know, not based on the published paper.

Q. Let's look at the next study from Hadland and colleagues. This is --

THE COURT: By the way, go back to the last one for one second.

MR. REISMAN: Yes.

THE COURT: It reads: "These findings should prompt the examination of industry influences on opioid prescribing."

It says it should prompt this kind of an examination/investigation.

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Was there a follow-up on that?

THE WITNESS: There were several other studies published from the same data that examines the industry influences.

THE COURT: But the only conclusion is that the findings should prompt an examination.

THE WITNESS: Yes.

THE COURT: Okay. Thank you. By the way, does the article say who was to conduct the examination?

THE WITNESS: That's not specified in the paper.

THE COURT: Okay. Thank you.

BY MR. REISMAN:

Q. So this is Demo 49. I correct myself. It's Demo 51.

Is this study -- was this done, published by Hadland in 2018, a year after -- actually, you know, let's hold this for a moment. And I want to ask you about the prior study.

MR. REISMAN: Can we bring the slide back up. Yeah, if we can skip to the end.

Okay. So, Sal, if you could hand out

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Demo 49.

BY MR. REISMAN:

Q. So is this study that was published in 2018 in JAMA Internal Medicine, is it titled, "Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing"?

A Yes.

Q. And this is the same Hadland who published the study that we just looked at a year earlier; is that right?

A The same first author, yes.

Q. So what did Hadland do in this study in 2018?

A So this study linked two different databases. One is the same Open Payments database that we were -- that was the topic of the American Journal of Public Health paper.

And then they looked at that in association with the Medicare Part D opioid prescriber summary file to correlate the marketing practices with prescription claims for Medicare beneficiaries.

Q. What did Hadland find in this study?

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2 A They found an association between the,
3 the amount of money that doctors received from
4 opioid manufacturers with subsequent opioid
5 prescribing.

6 Q. The slide that we're showing right now
7 is drawn from the article itself.

8 Can you explain to the Court what this
9 slide shows?

10 A Yes. This is the association between
11 the number of meals received in 2014 and the number
12 of opioid claims in 2015 from those same physicians
13 based on the number of meals that they received.

14 Q. Does it show that the more meals that
15 physicians received from opioid industry sales
16 representatives, the more opioids they prescribed?

17 A Yes. This would be consistent with
18 dose-response.

19 Q. Does this study, the 2018 study mention
20 any specific manufacturers of opioids?

21 A Yes.

22 Q. Which ones?

23 A It mentions the three companies with the
24 highest payment totals: Insys Therapeutics, Teva
25 Pharmaceuticals, and Janssen Pharmaceuticals.

1
2 Q. Let's move to the last slide, and we
3 already marked this for demonstrative purposes. The
4 study is Demo 51.

5 Is this a study that Hadland published
6 last year in JAMA Open?

7 A Yes.

8 Q. And is this one titled, "Association of
9 Pharmaceutical Industry Marketing of Opioid Products
10 With Mortality From Opioid-Related Overdoses"?

11 A Yes.

12 Q. What did Hadland and colleagues do in
13 this study?

14 A So similar to the prior study where
15 different databases were linked, this study used the
16 same Open Payments database and linked it with the
17 CDC WONDER data, the same mortality data that I
18 published in my report.

19 Q. What did the researchers conclude?

20 A They concluded that there was an
21 association between the amount of money spent on
22 opioid marketing and opioid-related harms in terms
23 of prescription opioid overdoses in those same areas
24 that were highly saturated with marketing dollars.

25 Q. So in this Hadland 2019 study, did the

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researchers build on the articles they published in 2018 and 2017?

A Yes.

Q. Did you, in your work on this case, evaluate the marketing materials of any manufacturer Defendant?

A No.

Q. Why not?

A Because that's not part of the epidemiological science that I relied on.

Q. Did Hadland and colleagues in these studies that we just looked at evaluate the marketing materials of any manufacturer?

A It's not in the study.

Q. What did they evaluate?

A They evaluated the Open Payments database.

THE COURT: By the way, these authors in Demo 51, are they epidemiologists or something else?

THE WITNESS: I am familiar with several of the authors who are -- who have Ph.D.s in epidemiology. I don't know the qualifications of all the authors, but many

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Q. Yes.

A No.

Q. Have you done any analysis of whether any of the distributor Defendants, take McKesson, if they had decided not to ship prescription opioids and another distributor had stepped in, whether the level of opioid harm would have been any different in the State of New York?

A I'm sorry, can you breakdown --

Q. Sure.

A Okay. So one distributor stops --

Q. Yes, and another distributor steps in, would the level of opioid harm had been any different?

A No.

Q. You haven't done that analysis?

A No.

Q. And you talked about marketing at the end of your opinions, I just want to ask you a couple of questions on marketing.

You don't know of a single time when McKesson, Cardinal, ABDC, one of the chain pharmacies gave marketing materials to a doctor in New York State, correct?

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A No.

Q. "No," you don't no that?

A I don't know that.

Q. You don't know of a single time when McKesson, Cardinal, ABDC, a chain pharmacy prepared specific marketing materials for doctors or patients, correct?

A That's correct.

Q. And the literature you've seen in terms of talking about marketing and points to entities other than McKesson, Cardinal, ABDC and chain pharmacies as conducting marketing to physicians regarding prescription opioids; is that correct?

A That's right.

Q. Do you agree that the opioid crisis was caused by multiple different factors?

A Yes.

Q. Would you agree that there are multiple interrelated and deeply rooted social and economic determinants of the U.S. opioid overdose crisis?

A Among others, yes.

Q. And in your work you've not attempted to assign percentages of responsibility for the opioid crisis in New York to Cardinal or McKesson or ABDC

adolescents.

By the way, is this study performed, in your view, using generally accepted methods?

A Yes.

Q. It says: "Adolescents who indicated medical use without a history of --" and I'm going to fill in the acronyms, tell me if I get it wrong. So let's start again.

"Adolescents who indicated medical use without a history of nonmedical use of prescription opioids did not differ from adolescents with no history of medical use of prescription opioids or nonmedical use of prescription opioids in the odds of alcohol use disorder, cannabis use disorder or other drug use disorder."

Did I read that correctly? Fill in any acronyms.

A Generally.

Q. And do you agree with that finding in this study, is that a reasonable interpretation of the data in the study; yes or no?

A Um, I think that I would have written it differently, so no.

Q. Is it wrong in your view?

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A It's not wrong.

Q. Can you point me to a contrary study showing individuals who use prescription opioids only medically have higher rates of heroin use?

A Sorry, say that again.

Q. Can you point me to a contrary cite showing individuals -- actually, no. I think I just asked you this question, so I'm going to move on.

I've asked you now about medical use prescription opioids, so I want to move over to nonmedical use of prescription opioids. Those 16 studies that you cited.

Do you consider each of those studies to be reliable when conducted using generally accepted methods?

A Yes.

Q. Going back to that distinction we drew between causation and association, am I accurate that none of those studies make the step of going beyond association to causation?

A No one study alone, no.

Q. None of them collectively, correct?

A Collectively, I think that's up to the epidemiologist.

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Q. Does anyone of those studies say, looking at our study and all other studies, we're now willing to conclude causation?

A Not those words.

Q. Do any of them go beyond association?

A I think they generally accept the well-accepted principle that prescription opioid use is a risk factor for heroin use.

Q. Do they go beyond association; just yes or no?

A Um, I would say yes.

Q. Okay. Well, let's look at what they say now.

MR. SCHMIDT: May I approach, your Honor.

THE COURT: Yes.

Q. I'm going to give you two things. One is a demonstrative that I prepared, and I don't think that you need to look at the study, but if you would like to look at the study, I've given you a set of the studies on this demonstrative --

A Thank you.

Q. -- and they're tabbed.

The demonstrative is four of the 16

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1 studies, you cite language from the studies. If you
2 can put it up on the screen, Demonstrative Exhibit
3 1, and I think we were using letters, so I'll mark
4 this as Defendant's Exhibit A -- I guess I'll mark
5 it as Defendant's Exhibit B, Exhibit A would be the
6 New York document encouraging opioid use that we
7 looked at earlier.
8

9 Do you recognize these four studies as
10 four of the 16 studies you looked at?

11 A Yes.

12 Q. And just very quickly (READING:)

13 (Khosla) 2011. Temporality and causal
14 associations could not be determined.

15 (Becker) 2008. While we were able to
16 describe associations, we are not able to ascribe
17 causality.

18 (Grau) 2007. A second limitation is the
19 cross-sectional nature of this study, which
20 precludes the possibility of establishing causal
21 relationships.

22 (Havens) 2009. Causal inferences could
23 not be made.

24 Did I read those excerpts right?

25 A Yes.

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2 Q. Do you agree with those statements as
3 made in the context of those studies; yes or no?

4 A Yes.

5 Q. And are you aware of any study that goes
6 farther and says we do find causation, we do find
7 more than an association?

8 A I think if you look at the language of
9 the discussion section, you know, limitations of the
10 studies aside, I think there is generally accepted
11 language that prescription opioid use is a risk
12 factor for heroin use.

13 Q. It's important to consider the
14 limitations, right?

15 A Yes.

16 Q. Do you know of any study that actually
17 says we believe there is causation between earlier
18 nonmedical prescription opioid use and later heroin
19 use, where it comes to a specific conclusion, it
20 goes beyond association and concludes causation?

21 A No.

22 Q. Can you point me to any study that
23 states there's general acceptance that nonmedical
24 prescription opioid use causes heroin use or illegal
25 fentanyl use?

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2 A I would need to go back to the studies.
3 I mean, off the top of my head, I don't have
4 specific sentences.

5 Q. Is there one you can point me to from
6 your work; just yes or no?

7 A Not off the top of my head.

8 MR. SCHMIDT: Let me show you one other
9 study you looked at. I'll mark this -- if I
10 may approach -- Defendant's Exhibit C.

11 THE COURT: Yes.

12 Q. Do you recognize this as a 2016 New
13 England Journal of Medicine, that's one of your 16
14 studies that you cite?

15 A Yes.

16 Q. This one, the lead author is Compton,
17 and if you look at the heading it's actually a
18 review article, correct?

19 A Yes.

20 Q. It's reviewing the literature that
21 existed at the time of this publication.

22 A Yes.

23 Q. Are you aware that it reviews 14 of the
24 16 studies that you cite in your report?

25 A Yes.

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2 Q. If we look at page 3 of this document
3 there's a heading that says: Heroin Use Among
4 People Who Use Prescription Opioids Nonmedically; do
5 you see that?

6 A Yes.

7 Q. Then a little further down, or actually
8 right below that, I'm sorry, it says: "Studies that
9 address the patterns of heroin use in nonmedical
10 users of prescription opioids are mostly
11 observational and descriptive; i.e.,
12 nonexperimental. Thus, conclusions about cause and
13 effect are uncertain.

14 Yet, certain consistent findings of a
15 positive association between nonmedical use of
16 prescription opioids and heroin use are highly
17 suggestive and plausible, given the common
18 pharmacologic principles described above?"

19 Did I read that correctly?

20 A Yes, you did.

21 Q. I want to point you to their later
22 conclusion and ask you about that. Can you go to
23 the fifth page of this article, please. And right
24 before the heading on the right, down at the bottom
25 of this page, if we could pull out the -- yeah, it

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2 says: "Taken in total, the available data suggests
3 that nonmedical prescription opioid use is neither
4 necessary nor sufficient for the initiation of
5 heroin use and that other factors are contributing
6 to the increase in the rate of heroin use and
7 related mortality."

8 Did I read that correctly?

9 A You did.

10 Q. Do you agree with that; yes or no?

11 A Yes.

12 Q. Is that a generally accepted view, in
13 your opinion?

14 A Yes, absolutely.

15 Q. And "necessary" means all cases of the
16 outcome have a risk factor, correct?

17 A That's right.

18 Q. "Sufficient" means by itself it can
19 bring it about, correct?

20 A That's right.

21 Q. We talked earlier about one of the other
22 factors or some of the other factors: the price of
23 heroin, the availability of heroin, the purity of
24 heroin; do you recall us touching on that?

25 A Yes.

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minutes ago, you asked a question about 2000 -- going back to 2007, and see if I have this right, I believe you put a question to the doctor that based upon the -- we'll call it the comments or statements of the, I believe the FDA, right, whether or not that had a connection to the marketing activities of the Defendants; was that about it?

MR. REISMAN: I'm not sure that was it. I was referring to marketing statements by the manufacturer Defendants.

THE COURT: Which came from where?

MR. REISMAN: It came from the manufacturers themselves.

THE COURT: What spawned, in your line, what spawned these marketing statements in or about 2007?

MR. REISMAN: Well, they were in materials, and they were in studies that were sponsored by the manufacturers.

THE COURT: And what allowed -- what was the license, let's say, for the Defendant manufacturers to issue those statements?

MR. REISMAN: Well, I don't think they